Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model): *Estimation of Dietary Lead Exposure for U.S. Children*

Peer Review Report

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EXECUTIVE SUMMARY

The Peer Review Panel (herein referred to as Panel) reviewed a document titled *Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), Estimation of Dietary Lead Exposure for U.S. Children* (herein referred to as the Update Document) to address 17 charge questions regarding the information contained in the document.

The Update Document presented a summary of the published literature and an analysis of the available data regarding nationally representative dietary lead intakes for children in the United States.

This Peer Review Report is intended to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

The Panel's review resulted in an editorial revision of the Update Document. The Panel's findings are summarized below in Section 2.2 Summary of Findings and Section 3.0 Results. The revised final Update document may be found at http://epa.gov/superfund/lead/trw.htm.

1.0 INTRODUCTION

1.1 Background

The default background values for the *Dietary Lead Intake* variable in the IEUBK model represent central tendency estimates for lead intake from food in the absence of exposures at the site being assessed. Initially, these default consumption rates were derived from the U.S. Department of Agriculture's 1977-78 U.S. Nationwide Food Consumption Survey (NFCS; USDA, 1984) and the U.S. Department of Health and Human Services 1976-80 National Health and Nutrition Examination Survey (NHANES; U.S. DHHS, 1983). Of the approximately [redacted] foods obtained from the NFCS and NHANES surveys, a representative list of [redacted] commonly eaten foods in the U.S. was then paired with dietary-lead concentration data from the U.S. Food and Drug Administration's (U.S. FDA) Total Diet Study (TDS; 1973-82) to predict dietary lead ingestion (Pennington, 1983). The U.S. EPA (1994a,b) later mapped these dietary lead intake rates to the IEUBK model's [redacted] age-specific food categories. The U.S. EPA prepared updated estimates for this parameter in 2003 and 2006 using data from the TDS and the NHANES. Current default values for the *Dietary Lead Intake* variable in the IEUBK model are based on three cycles of NHANES data (1988-1994; U.S. CDC, 1997), eight years of TDS data (1995-2003; U.S. FDA, 2006), and the method discussed by Pennington (1983).

The purpose of the Update Document was to provide a recommendation for revising the age-specific *Dietary Lead Intake* variable in the IEUBK model using: 1) a more representative methodology for estimating food consumption, and 2) more recent TDS and NHANES survey data. Updating the IEUBK model default values may be considered appropriate if evidence is sufficient to indicate that a newer, more representative data and methodologies for calculating dietary lead intakes are available that would be more protective for site risk assessment.

The Update Document presents an analysis of the available data regarding dietary lead intakes for children. The principal objectives of the review and data analysis were as were to:

1. Identify published literature potentially relevant to estimating dietary lead intakes in children. Select studies that meet predetermined quality considerations.

2. Evaluate data contained in the pertinent national databases (*i.e.*, dietary and food-Pb concentration data) to examine whether they are adequate and sufficient to conclude that the current IEUBK model default values for dietary lead intakes are representative (or not) for residential scenarios at Superfund sites.

3. Consider use of these data, if adequate and sufficient, to recommend a quantitative central tendency estimates for dietary lead intakes for use in the IEUBK model.

This Peer Review Report was prepared to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

2.0 PEER REVIEW PROCESS

2.1 Peer Review Charge

The Update Document qualifies as a technical document and is eligible for an independent peer review of the content. U.S. EPA contracted Environmental Management Support, Inc. (EMS) to conduct an independent peer review of the Update Document. EMS conducted the review of the technical document in accordance with the U.S. EPA's Science Policy Council Peer Review Handbook (U.S. EPA, 2006). Management of the review consisted of the following general activities:

- Identified areas of expertise necessary for a scientifically rigorous review.
- Identified a list of candidate expert peer reviewers.
- Evaluated the expertise of each of the candidate expert peer reviewers.
- Created a short list of candidate expert peer reviewers.
- Determined the interest and availability of the short list of candidate expert peer reviewers.
- Determined for each of the remaining list of candidate peer reviewers any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality; excluding candidates with either.
- Finalized a team of three expert peer reviewers.
- Developed charge questions in conjunction with U.S. EPA for the conduct of the peer review.
- Initiated the review.
- Coordinated the peer reviewers to finalize their written reviews.

The peer review was conducted as a letter review. Each reviewer was provided a copy of the Update Document and charge questions.

In seeking candidates to serve as peer reviewers, as well as selecting the final team of reviewers, an effort was made to include individuals with expertise in one of more of the areas identified by U.S. EPA:

- Dietary Exposure to Lead
- National Cancer Institute Models
- Exposure Assessment or Risk Assessment
- Toxicology
- Mathematics or Statistics
- Epidemiology, Environmental Health, Science, or Environmental Engineering

The final team of expert reviewers on the Panel consisted of the following:

- Dr. Serap Erdal, University of Illinois – Chicago School of Public Health;
- Dr. Rufus Chaney, U.S. Department of Agriculture; and
- Dr. Janet Tooze, Wake Forest University School of Medicine.

The TRW Lead Committee thanks the Panel for providing valuable comments on the Update Document.

Efforts were made to ensure that each Panel member was allowed sufficient time to complete their review. Upon receipt by EMS, each letter review was examined and formatted for delivery to U.S. EPA. A brief summary of the Panel's findings is included in Section 3.1. U.S. EPA's charge to the Panel and a summary of the Panel's findings is included below. A summary of the Panel's comments are included as an appendix to this document.

2.2 Summary of Findings

- The Panel agreed that the databases used for the analysis were appropriate, but each reviewer noted that the data presented in the Update Document should be thoroughly reviewed. One reviewer recommended additional publications that could be included in the Update Document's analysis.

- Each reviewer recommended reorganizing and adding additional details to the Update Document to improve the clarity. Two of the three reviewers acknowledged that the scientific evidence presented was appropriate and adequate to answer questions about the current IEUBK model default value.

3.0 RESULTS

The Panel's review comments were reviewed and considered by the TRW Lead Committee and resulted primarily in an editorial revision and a review of numerical values in the Update Document. The Panel recommended revising the Update Document's organization, but did not alter the scientific methodologies, including the databases used. The dietary Pb intakes, however, were updated after reviewing the numerical values (Section 3.1). In addition to the reorganization, the Update Document text was added to clarify the objective and findings based on the comments received from the Panel. Sections were retitled and reorganized as the following:

Peer Review Draft	Revised Draft
Overview	Overview
Analysis	Introduction
References	Technical Analysis

Uncertainty
Results
Recommendations for the IEUBK
Model
Impact on the IEUBK Model
Predictions
References

The Panel provided a combined total of 72 comments. The majority of the comments were directed towards reorganizing the document for clarity; however, there were additional comments regarding numerical values presented in the document. Each comment was reviewed by the TRW Lead Committee and resolutions were incorporated into a revised draft.

Based on the review of the Update Document, the Panel's overall recommendation for the update of the *Dietary Lead Intake* variable in the IEUBK model was: **Acceptable with major revision (as outlined).**

The Appendix presents a summary of peer review questions and comments. The revised final Update Document may be found at http://epa.gov/superfund/lead/trw.htm.

3.1 Selected Comments

Representative comments were selected to demonstrate the process and overall consensus of the peer review.

COMMENT (1): The document should be completely reorganized and should have three separate sections for lead concentration in food, food consumption rate, and dietary intake. Each section should have subsections for data sources utilized as aforementioned above, data analysis techniques, data analysis results, proposed values and discussion outlining strengths and weaknesses of proposed values and the impact of these strengths and weaknesses on the IEUBK model estimates, preferably quantitatively, but, at least, qualitatively.

COMMENT (2): I am not convinced that this analysis was done correctly due to the lack of detail in the document and due to some of the values in Table 3.

Response to Comments 1 & 2: The Update Document was reorganized for clarity and additional sections and text were added describing how the dietary lead intake values were calculated. Specifically, 'Introduction', 'Technical Analysis', 'Uncertainty', 'Results', 'Recommendations for the IEUBK Model' and 'Impacts on the IEUBK Model Predictions' sections were added. In the text below black indicates original text, red indicates new text, strikeout indicates deleted text.

Previous text:
Dietary lead intake was calculated as the mean daily food category consumption per age group (Table 2) and IEUBK model food group (as determined by the NCI method), multiplied by the mean lead concentration for the IEUBK model food group (Table 3). The dietary lead intake for each age group is equal to the sum of the lead intake from each IEUBK model food group.

The IEUBK model (Version 1.1, Build 11) default dietary lead intakes and the intakes computed using the more recent TDS lead concentration data and food consumption rates estimated by the NCI method (Table 3). As shown in Table A-2, the increase in the recommended dietary lead intake values relative to the IEUBK model default values is largely due to an increase in the estimated average daily dietary consumption values relative to the IEUBK model's default values, which were based on Pennington (1983), rather than higher dietary lead concentrations (Table 4).

New Section Added (new Tables and Figures are not shown):
TECHNICAL ANALYSIS

The annual mean lead concentration measured in TDS foods between 1995-2005 is fairly constant, varying within a relatively narrow range (Figure 1). For this analysis, these data were pooled to increase the sample size for each of the IEUBK model food categories. The TDS foods were mapped to the Exposure Core Food (ECF) groups as shown in Figure 2. ECF groups with more than one TDS food mapped to them were assigned the mean lead concentration for those TDS foods. Non-detects were replaced by [redacted] the limit of detection, and results reported as 'trace' (i.e., between the limit of detection and the limit of quantitation) were not adjusted (Table 2). This was applied only to the TDS data. The mean lead concentration for each of the [redacted] IEUBK model food groups was calculated as the weighted average of the lead concentrations of the ECF groups that are mapped to the IEUBK model food group. In calculating the weighted average, the weight (grams) for a particular ECF food that was consumed (as reported on the WWEIA survey) was divided by the mass (grams) of all ECF foods eaten in a given IEUBK model category. The estimated mean lead concentration (µg Pb/gram food) for each IEUBK model food category is provided in Table 3.

Information on dietary intakes (grams food/day) for children [redacted] years of age was extracted from the NHANES WWEIA data files (U.S. CDC, 2010a,b). Data from the two most recent [redacted] year cycles (2003-04 & 2005-06)[1] were used, in accordance with U.S. CDC recommendations (U.S. CDC, 2006). The individual food consumption rates were mapped to one of the IEUBK model food category, via the ECF groups, as shown in Figures 2 and 3.

[1]The 2003-04 & 2005-06 dietary data were the most recent available data at the time this research was initiated.

The WWEIA database included a very small number of children [redacted] months and older whose parents reported them as consuming infant food and formula. Because data for fewer than [redacted] children were available, estimates for formula and infant food consumption rates for ages [redacted] months and older are not provided. The effect of omitting these data is addressed in the Uncertainty section.

Mean daily ingestion rates (grams food/day) were calculated for each IEUBK model food category using the NCI method (Table 4). Estimated daily lead intakes (µg Pb/day) were calculated by multiplying the estimated ingestion rates by the mean lead concentration (Table 5). The proposed dietary Pb intake rates provided in Table 1 were then calculated as the sum of the [redacted] IEUBK model food category-specific Pb intake rates.

SAS® software (Version 9.1) was used to estimate lead concentration and dietary intakes. Parameter estimates used the sample weights provided in the NHANES data files (U.S. CDC, 2010a,b). The sample weights accounted for the unequal probabilities of selection of survey participants, the non-response of some participants, and were adjusted to population controls. While the NCI method estimates approximate standard errors for the regression model parameters, the current version does not accept the NHANES masked-variance units that account for the multistage sampling design which would be required to produce more reliable standard errors for parameter estimates.

COMMENT (3): Although the rationale for considering change may be correct, the data are not correct, so one cannot say the present text is "clear" because it has evident errors or problems. The large error in assigning foods to the IEUBK food groups makes all else questionable. And the large error in use of the FDA food composition data makes all discussion questionable. So it cannot be clear in this version

COMMENT (4): Reviewer found significant errors in processing the FDA food Pb concentration data and the NCI food intake data (explained below). Thus, the scientific evidence has not been synthesized appropriately and the document must be revised to be technically correct. In addition, the cited document (U.S. EPA. 2011. Technical Support Document for dietary lead intake in the Integrated Exposure Uptake Biokinetic Model for Lead in Children. Prepared by SRC for U.S. EPA Office of Superfund Remediation and Technology Innovation under contract GS-00F-0019L.) was not provided, so reviewer did not have sufficient information about how EPA used the NCI food intake data and the FDA food Pb concentration data to calculate the IEUBK food group Pb concentrations.

Response to Comments 3 & 4: The values that were discussed in the text and in tables were reviewed for accuracy. Additional tables and figures were added. Proposed values were updated with corrected values. Figures 2 and 3 were added to illustrate

the food code mapping procedure. In the text below black indicates original text, red indicates new text, strikeout indicates deleted text.

Table 47. Comparison between IEUBK model default values for average daily dietary lead intake (µg Pb/day), food consumption and consumption-weighted average lead concentration. ~~Comparing the increases in consumption and concentration to intake, it is clear the increase in consumption is the primary reason for the increase in the estimate of dietary lead intake.~~

Parameter	Age Category ~~Range~~ (months)						
	[redacted]						
IEUBK Model Default Dietary ~~I~~intake Rates ~~in IEUBK V1.1, Build 11~~ (µg Pb/day)[a]	[redacted]						
Proposed Dietary Intake Rates ~~estimated by the NCI method~~ (µg/Pb/day)[b]	[redacted]						
Food Intake ~~Increase in intake (NCI – default)~~ (% change)[e]	[redacted]						
Mean Food-Pb Concentration ~~Increase in average food concentration (above 2006 update)~~ (% change)[dc]	[redacted]						
Relative Consumption Rate ~~Increase in consumption~~ (NCI - default) (%)[ed]	[redacted]						

[a]Current IEUBK model (v. 1.1, build 11) default values. Values were derived using data from the TDS (1995-2003; U.S. FDA, 2006), NHANES WWEIA (1988-1994, U.S. CDC, 1997), and the methodology discussed in U.S. EPA (1994a,b) and Pennington (1983).

[b]Values were derived using data from the data from the TDS (1995-2005; U.S. FDA, 2010), NHANES WWEIA (1995-2005), and the NCI Method (Parsons, 2009; Tooze et al., 2006)

[c]Values were calculated using the consumption-weighted average concentrations.

[d]Calculated as the consumption values estimated by the NCI method with data from NHANES/WWEIA (2003-06;U.S. CDC 2010 a, b), relative to the default consumption values in the current IEUBK model (v.1.1, build 11) (U.S. EPA 1994a,b).

~~[a]Values calculated using the consumption values from Pennington, 1983 (US EPA, 1994 a, b) and food residue data from the Total Dietary Survey Market Baskets collected from 1995-2003.~~

[b]Values calcualted using the NCI method (Parsons, 2009; Tooze et al., 2006) and data from National Health and Nutrition Examination Survey, What We Eat In America 2003-04 & 2005-06 (US CDC 2010 a,b) and Total Dietary Survey Market Baskets collected from 1995-2005.

[c]Percent increase in intake, calculated as: (column 3 – column 2) / column2.

[d]Values were calculated using the consumption-weighted average concentrations, using the food residue and consumption data that were used to estimate the default values (i.e., column 2) and the recommended values (column 3).

[e]Calculated as the consumption values estimated by the NCI method with data from NHANES/WWEIA 2003-04 & 2005-06 (US CDC 2010 a, b), relative to the default consumption values in IEUBK V1.1, Build 11 (US EPA 1994 a, b).

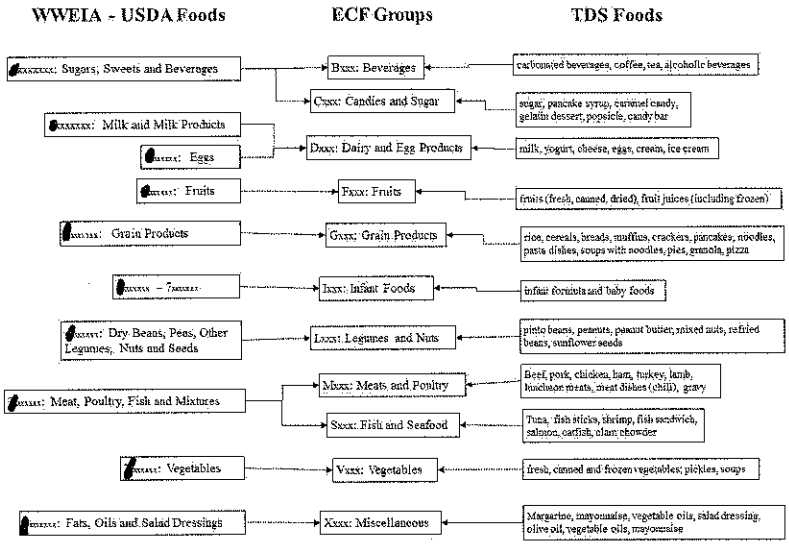

Figure 2. Mapping food consumption data to food residue data using the approach developed by Tomerlin et al. (1997). The What We Eat In America (WWEIA) dietary survey is administered during the National Health and Nutrition Examination Survey. The Exposure Core Food (ECF) groups were created for the U.S. EPA dietary exposure potential model (Tomerlin et al., 1997) to connect consumption data from the 1997-78 and 1987-88 Nationwide Food Consumption Surveys and the 1989-1992 USDA Continuing Surveys of Food Intake by Individuals to food residue data from the U.S. Food and Drug Administration Total Diet Study (TDS). Additional USDA and TDS foods were mapped to ECF groups by Lockwood et al. (1998) and the current research. The FDA's TDS has been monitoring contaminant levels in foods since 1961 (Egan, 2002, 2007) through their 'Market Basket' surveys that are conducted in different regions of the country on a quarterly basis (i.e., every 3 months).

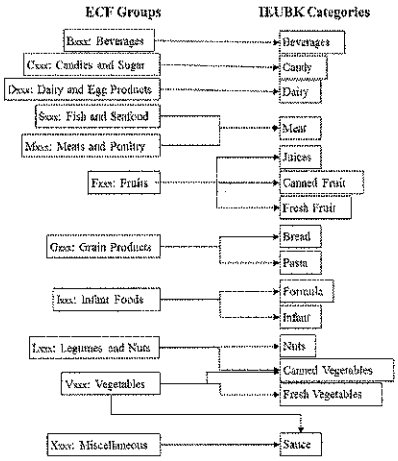

Figure 3. Mapping the Exposure Core Food (ECF) codes (Tomerlin et al., 1997) to the IEUBK model food groups. In most cases, each ECF code could be mapped to a single IEUBK model food group. In cases where an ECF code contained a mixture of foods from different IEUBK model categories, the ECF code was assigned to the IEUBK model category based on what appeared to be the main ingredient (e.g., the total mass of a beef stew dish was mapped to the IEUBK model meat category).

COMMENT (6): In addition, reviewer looked at the dietary Pb intake estimates used in the original (1994) IEUBK model and the numbers were similar to these present proposed numbers, well above the previous version of IEUBK being revised with this proposed change. Reviewer suggests that the document show in Table 1 all of the different sets of Pb intake estimates used in the many versions of the IEUBK model since 1994, not just the immediately preceding value and the proposed value.

Response: Table 1 was revised, and a summary (Table 6) was added to address this comment. In the text below black indicates original text, red indicates new text, strikeout indicates deleted text.

Table 1. Comparison of age-specific dietary Pb intake values.

Source	IEUBK Model Age Range (months)	Dietary Pb Intake Input Values (µg/day)	Basis for Age-Specific Value
IEUBK Model Default (version 1.1, build 11)	[redacted]	[redacted]	Calculated using the consumption values from Pennington, 1983 (US EPA, 1994 a, b) and food residue data from the Total Dietary Survey Market Baskets collected from 1995-2003.
Recommended Dietary Intake Values[a]	[redacted]	[redacted]	Values estimated using the NCI method (Parsons, 2009; Tooze et al., 2006)

[a]Data from National Health and Nutrition Examination Survey, What We Eat In America 2003-04 & 2005-06 (U.S. CDC, 2010 a,b) and Total Dietary Survey Market Baskets collected from 1995-2005 (FDA, 2010).

Revised Table 1. Comparison of age-specific dietary lead intake rates (µg Pb/day) for use in the IEUBK model.

Source	Age Category (months)							Basis for Age-Specific Value
	[redacted]							
IEUBK Model Default[a]	[redacted]							*Dietary Pb Concentration 1995-2003 TDS (U.S. FDA, 2006)* *Dietary Intake 1988-1994 NHANES (U.S. CDC,*

								1997) Methodology Pennington, 1983, U.S. EPA, 1994a,b
Proposed Dietary Intake Values	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dietary Pb Concentration 1995-2005 TDS (U.S. FDA, 2010) Dietary Intake 2003-06 NHANES WWEIA (U.S. CDC, 2010 a,b) Methodology NCI Method (Parsons, 2009; Tooze et al., 2006)

TDS: Total Diet Study; NHANES: National Health and Nutrition Examination Survey; WWEIA: What We Eat in America survey; NCI: National Cancer Institute

[a]IEUBK model v. 1.1, build 11.

Table 6. Effects of changing the Dietary Lead Intake (µg Pb/day) in the IEUBK model.

IEUBK Model Version	Basis for Age-Specific Value	Age Category (months)							GM PbB[a] (µg/dL)	P10 (% Above)	PRG for % NTE	
		[redacted]	≤ [redacted]	≤	≤	≤	≤	≤			[redacted] µg/dL	µg/dL
1994 Default[a]	1965-82 TDS (as cited in Pennington, 1983); 1977-78 NFCS (USDA, 1984); 1976-1980 NHANES (U.S. DHHS, 1983); Pennington, 1983; U.S. EPA, 1994a,b	[redacted]										
2003 Update[b]	1991-1999 TDS (U.S. FDA, 2001); 1988-1994 NHANES WWEIA (U.S. CDC, 1997); Pennington, 1983; U.S. EPA, 2009, 1994a,b	[redacted]										
2006 Update[c]	1995-2003 TDS (U.S. FDA, 2006) ; 1988-1994 NHANES (U.S. CDC, 1997); Pennington, 1983; U.S. EPA, 2009, 1994a,b	[redacted]										
Proposed Update[d]	1995-2005 TDS (U.S. FDA, 2010); 2003-06 NHANES WWEIA (U.S. CDC, 2010 a,b) NCI Method (Parsons, 2009; Tooze et al., 2006)	[redacted]										

GM: geometric mean; PbB: blood lead concentration; P10: probability children's PbB will exceed [redacted] µg/dL; PRG: preliminary remediation goal; NTE: not to exceed; TDS: Total Diet Study; NFCS: U.S. Nationwide Food Consumption Survey; NHANES: National Health and Nutrition Examination Survey; NCI: National Cancer Institute

[a]Calculated values were based on IEUBK model v. 1., build [redacted] default input values, with the exception of the dietary intake rates specified in the table.

COMMENT (7):There are some errors in the way in which the NHANES data are described. It should read, "NHANES is a continuous annual study...that is released in ...two-year cycles." Also, it queries both food and beverages. The survey is done annually, but data are only released every [redacted] years. I agree with the use of the NHANES data. There is not enough background given in this document on the TDS to determine if it is appropriate to determine lead levels in foods and nutrients, but from what is written, it appears it would be appropriate.

Response: The text was reviewed and additional details were added. In the text below black indicates original text, red indicates new text, strikeout indicates deleted text.

> The TDS is an *ongoing U.S. FDA program* ~~annual survey~~ that *has* measure*d*~~s~~ the level of nutrients and contaminants, including lead, in foods consumed in the ~~United States.~~ *U.S. since 1961 (Egan, 2002). Using data from nationwide food consumption surveys, a list of foods that represents the diet of the U.S. population is routinely updated to reflect current eating patterns (Egan, 2002, 2007). The data reflect contaminant levels in [redacted] foods as they are consumed. Ingredients required to prepare the TDS foods are purchased from grocery stores and supermarkets four times per year (once in each of four geographic regions of the country).*~~The most recent TDS data available at the time the analysis was initiated was from 2005. The concentration of lead has remained fairly constant since 1995; therefore, the TDS data from 1995-2005 were pooled for this analysis to increase confidence in the estimate of the mean lead concentration in each TDS food item.~~
>
> *The NHANES is a continuous survey* ~~*study of*~~ *that is designed to assess the health and nutritional status of children and adults in the U.S. (http://www.cdc.gov/nchs/nhanes.htm).* ~~*that is implemented as a continuous series of two-year surveys. Each two-year cycle of NHANES includes a dietary component called What We Eat in America (WWEIA) that is implemented by the U.S. Department of Agriculture's Food Surveys Research Group (FSRG) and the U.S. Department of Health and Human Services' National Center for Health Statistics (NCHS).*~~ *U.S. CDC releases data from the NHANES in 2-year increments as one dataset, and recommends using four or more years of data (i.e., two or more datasets) when estimating parameters for demographic sub-domains (U.S. CDC, 2006).*
>
> *The dietary component of the NHANES survey [i.e., What We Eat in America (WWEIA)] is conducted as a partnership between the USDA and the U.S. DHHS. The WWEIA includes two 24-hour dietary recall interviews* ~~*during which each respondent reports all foods, including portion sizes, they consumed during the prior day. Each food is assigned an FDA food code, which in turn was assigned to one of the IEUBK model's 15 food categories.*~~ *to query all foods and portion sizes consumed during the prior 24 hours. Although the recall is limited to foods consumed for a single day, it provides very detailed and reliable data (e.g., including brand names for certain foods; whether they were cooked in animal or vegetable fat). The second most commonly used dietary survey instrument is*

the food frequency questionnaire (FFQ) which typically collects information about food consumption over a much longer period of time (e.g., the year preceding the date of the interview). However, the FFQ typically collects only data on consumption frequency; information about the quantity of food consumption, which is required to estimate dietary intake rates, is not collected.

Dodd et al. (2006) provides an overview of the challenges of estimating long-term average dietary intake from [redacted]-hour recall data, as well as the development of statistical methods to meet these challenges. Briefly, surveys are dependent upon memory. Dodd et al. (2006) demonstrated that the reliability and resolution of a dietary survey decreases as the duration of the survey duration increases. Secondly, estimating long-term average daily consumption rates from short-term [redacted]-hour dietary recalls requires an assumption that the 24-hour recalls provide an unbiased estimate of population intake, provided a sufficient amount of the recalls are collected (Dodd et al., 2006). Lastly, a major challenge in estimating dietary intake with [redacted]-hour recall data is the large within-person day-to-day variability in diet relative to the between-person variability.

4.0 REFERENCES

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Appendix – Peer Review Comments

CHARGE QUESTIONS to REVIEWERS

for Peer Review of

"Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Dietary Lead Exposure for U.S. Children*"

August 2012

U.S. Environmental Protection Agency (EPA). Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Dietary Lead Exposure for U.S. Children.*

EPA is seeking external peer review of the scientific basis supporting the update of several exposure variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model). The IEUBK model was developed to evaluate exposure of children ([redacted] months) to lead and is used to assess risk and support environmental cleanup decisions at current or potential Superfund sites. The IEUBK model is maintained by U.S. EPA's Technical Review Workgroup Lead Committee (TRW).

The TRW has identified recent data that provide a more scientifically sound basis to develop nationally-representative, age-group specific default values for intake rates of lead in children. Given the available data, the TRW recommends updating the IEUBK model default values for the bioavailability of lead in soil and dust, water lead concentration in the United States, as well as water consumption, dietary consumption, and ventilation rates in children in the United States.

The current draft recommendations include updates to the bioavailability of lead in soil and dust, national drinking water lead concentration, as well as age-specific water, air, and food intake values. Because site-specific information is generally preferred to default values for exposure variables in the IEUBK model, it is anticipated that some of these defaults may be replaced with site-specific information. The goal of this review is to ensure that default values for exposure variables in the IEUBK model are scientifically sound and representative of reasonably current lead exposure in the United States.

Expertise Required:
Peer reviewers should have an advanced degree and/or experience in toxicology, mathematics, statistics, epidemiology, environmental health, environmental science, or environmental engineering. EPA is seeking peer reviewers with expertise in: (1) dietary exposure to lead; (2)

National Cancer Institute (NCI) models; (3) either exposure assessment or risk assessment.
Familiarity with the IEUBK model is beneficial. No more than one candidate peer reviewer will be selected from the same agency, consulting firm, or university.

Peer Review Charge Questions:
As a peer reviewer, you are asked to assess the adequacy of this document to provide a clear and concise explanation of the scientific issues regarding the evaluation of and recommendation for updating the IEUBK model. Please comment on the use of the approaches and methodologies to derive default values presented in the following technical document: *Estimation of Dietary Lead Exposure for U.S. Children.*

In evaluating the technical document: *Estimation of Dietary Lead Exposure for U.S. Children*, please respond to the charge questions below. If changes are to be made, please provide the technical basis for the proposed.

Section 1: General Charge Questions

1.1 QUESTION: Is the organization of the document appropriate and is the document logical, clear and concise? Has EPA clearly synthesized the scientific evidence for the updated IEUBK model input values?

COMMENT: The reviewers agreed that the national databases outlined in the Update Document were appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support the methodologies used. Furthermore, two of the three reviewers recommended a review of the calculations provided in the Update Document.

1.2 QUESTION: Does the evidence presented support implementing the revisions to IEUBK model as default values for the US?

COMMENT: The reviewers agreed that the national databases outlined in the Update Document were appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support the methodologies used. Furthermore, two of the three reviewers recommended a review of the calculations provided in the Update Document.

1.3 QUESTION: What are the strengths and weaknesses of approaches and methods employed given the available data?

COMMENT – Strengths: The reviewers agreed that the databases used to derive the proposed dietary intake values are more recent and robust than the current

IEUBK model default values. One of the three reviewers supported using the NCI method, but noted that additional information is needed on how it was implemented.

COMMENT – Weaknesses: The reviewers noted that the Update Document does not provide sufficient information on 1) how the proposed values were calculated and 2) how the food groups were defined for the IEUBK model. Two of the three reviewers requested additional information on the NCI method, and each reviewer also agreed that the document should be reorganized for clarity.

1.4 QUESTION: Given the data available, what additional technical considerations can you recommend in the derivation of default values? Is EPA using appropriate models, datasets and assumptions on which to base a scientifically credible decision?

COMMENT: The reviewers agreed that the national databases outlined in the Update Document were appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support the methodologies used. Furthermore, two of the three reviewers recommended a review of the calculations provided in the Update Document.

1.5 QUESTION: Are you aware of any other significant data/studies that are relevant and should be included or referenced in this document? Please identify any additional studies that should be considered in the assessment of the IEUBK model values.

COMMENT: One of the three reviewers provided three publications for inclusion:

Schell L.M., Denham M., Stark A.D., Ravenscroft J., Parsons P., Schulte E. 2004. Relationship between blood lead concentration and dietary intakes of infants from 3 to 12 months of age. Environ Research. 96 (3):264-273.

Stanek K., Wanton W., Angle C., Eskridge K., Kuehnenan A., Hanson C. 1998. Lead consumption of 19- and 36-month-old children as determined from duplicate diet collections: Nutrient intakes, blood lead levels, and effects on growth. J. Amer. Dietetic Association. 98(2) 155-158.

Section 2. Specific Charge Questions

This document recommends calculating dietary intake values using a non-linear regression model developed by the National Cancer Institute (NCI Method) and data obtained from U.S. CDC (2010a,b) and U.S. FDA (2010).

2.1 QUESTION: Do you agree with the rationale for using the Total Diet Survey data? NHANES data? Is the background information clearly presented?

COMMENT: The reviewers agreed that the national databases outlined in the Update Document were appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support the methodologies used.

2.1.1 Specifically, what are the strengths and weaknesses of these surveys?

COMMENT (Strengths): One of the reviewers noted that the primary strength of the NHANES survey is "that it is a representative sample of the US and utilizes very rigorous data collection procedures".

COMMENT (Weaknesses): Each reviewer agreed that further explanation/information should be presented. One reviewer noted that the uncertainty associated with the NHANES survey (e.g., self-reported, [redacted]-hour recall data) should be explained further. Two of the reviewers agreed that further explanation was needed for including two cycles of NHANES data (vs. four cycles).

2.1.2 Is this an appropriate measure of dietary intake in the United States?

COMMENT: The reviewers agreed that the national databases outlined in the Update Document were appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support the methodologies used. Furthermore, two of the three reviewers recommended a review of the calculations provided in the Update Document.

2.2 QUESTION: Is this an appropriate application of the NCI Method? Is the NCI methodology explained clearly?

COMMENT: Each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support

applying the NCI Method. One of the three reviewers did feel the NCI Method was appropriate to use without further explanation.

2.2.1 Do you agree with the use of a non-linear regression model to analyze the dietary intake rate as a function of age?

COMMENT: Each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support applying the NCI Method. One of the three reviewers did feel the NCI Method was appropriate to use without further explanation.

2.2.2 Specifically, what are the strengths and weaknesses of the non-linear regression method for this analysis? Please comment on the statistics used to derive the proposed values.

COMMENT (Strengths): One reviewer noted that the NCI Method is "able to adjust for random measurement error that is associated with collecting two days of 24-hour dietary recall" data.

COMMENT (Weaknesses): Two of the three reviewers agreed that more information is needed to determine if the values were calculated properly.

3.0 QUESTION: Is the comparison between the current IEUBK model values and the proposed values clear (Table 4)?

COMMENT: One reviewer stated, "Not completely".

3.1.1 Do you agree with the following: "Comparing the increases in consumption and concentration to intake, it is clear the increase in consumption is the primary reason for the increase in the estimate of dietary lead intake among children [redacted] months."

COMMENT: Each of the reviewers agreed – "Yes"; however, each reviewer also agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support this statement.

3.1.2 Is the rationale for this determination clearly presented?

COMMENT: Two of the three reviewers agreed that while the rationale may be correct, additional data are needed to clarify the proposed updated values. Each reviewer also agreed that the Update Document needs to be reorganized for clarity.

4.0 QUESTION: Does the document provide the adequate information needed to successfully update this variable in the IEUBK model?

COMMENT: Each of reviewers agreed – No.

5.0 QUESTION: Do you have any recommendations for additional analysis of the data? Please provide any additional data, concepts, or other considerations that would provide support for the age-specific values.

COMMENT: Each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support updating the IEUBK model default values. One reviewer noted that a two-dimensional mean analysis (food groups by age) would be beneficial, as well as the confidence percentiles (e.g., [redacted] and [redacted] of consumption estimates using the NCI Method. One reviewer recommended providing a comparison of the NCI Method predictions with probabilistic risk techniques.

6.0 Are there any elements missing that should be included or other information that would strengthen the document?

COMMENT: Each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support updating the IEUBK model default values. Specifically, the reviewers agreed that the document should have the following: 1) a list of the food codes that were used to create each food group, both for the NHANES data and for the TDS data; 2) TDS consumption values should be added; 3) data that supports the increase in average food concentration should be added; 4) details how the analysis was done (SAS macros used, what version, how implemented, subgroups) should be added.

Section 3: Recommendations

Based on your reading and analysis of the information provided, please identify and submit an explanation of your overall recommendation for the updating the dietary lead intakes in the IEUBK model.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance)

COMMENTS:

- *Reviewer 1: Acceptable with major revision (as indicated).*

- *Reviewer 2: Acceptable with major revision (as outlined). Acceptable with major revision (as outlined). I think that updating the consumption day values with the NHANES data is a good approach, and I think the NCI method is a good method to use to estimate the distribution of usual intake. I do, however, have serious concerns as to whether this approach was correctly implemented, and I cannot recommend this document as acceptable until these concerns are addressed.*

- *Reviewer 3: Acceptable with major revision (as indicated). Reviewer suggests that EPA revise and correct the document making all connections clear to readers and reviewers. The use of FDA Pb concentrations in the calculation of EPA food groups should be clear to readers, and how these were connected to the NCI food intake values should be clarified. If the remarkable intake of infant formula by [redacted] and [redacted] year old children is explained or corrected, the document may be useful. EPA should have checked with other Federal Agencies which develop and use food intake data before adopting the NCI method. FDA nor USDA have adopted this approach. Some discussion with these experts in needed to sort out how much more valid the NCI approach might be for [redacted] year old children should be expressed. It is not evident from the NCI papers or present text. With the miss-use of the FDA food Pb concentration data, reviewer could easily have concluded that the present document is not acceptable. However, it seems possible to sort out these problems identified and to correct them to achieve the levels of scientific quality expected in the IEUBK program.*